UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

ROBERT BRADBURN,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CASE NO. 3:19-cv-925-PPS-MGG
	)	
CR BARD, INC., *et al.*,	)	
	)	
Defendants.	)	

OPINION AND ORDER

This is a products liability lawsuit brought by plaintiff Robert Bradburn against C.R. Bard, a medical device company, its wholly owned subsidiary Bard Access Systems, Inc., and an unnamed set of "Does 1-10." For simplicity's sake, I'll refer to them collectively as Bard or the defendants. The amended complaint alleges that Bradburn had a medical device implanted in him which was manufactured and sold by Bard. Shortly thereafter, that device somehow migrated within Bradburn's body and injured him. Bard has moved to dismiss the amended complaint for a variety of different reasons. As discussed below, I agree with Bard on some fronts but disagree with it on others. Consequently, I'll grant its motion to dismiss in part, deny it in part, and allow the lawsuit to continue in a somewhat limited capacity.

Background

Because we are at the motion to dismiss stage, I must accept all factual allegations in the amended complaint as true and make all factual inferences from them

in favor of the plaintiff. The amended complaint is light on specifics, but the allegations sketch out the basic picture of what happened. Here's what Bradburn says happened: C.R. Bard, Inc., is a New Jersey-based medical device manufacturer. [DE 9, First Am. Compl. at ¶ 3.] Its wholly owned subsidiary is Bard Access Systems, Inc. which is based out of Utah. [*Id.* at ¶ 4.] One of Bard's products is the PowerPort M.R.I. Implantable Port. [*Id.* at ¶ 10.] The PowerPort "is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parental nutrition solutions, and blood products." [*Id.* at ¶ 11.] The idea is for the product to be implanted under a patient's skin to allow for easier access to administer intravenous medications, fluids, blood products, or the withdrawal of blood. For example, it is used to help deliver chemotherapy to cancer patients. [*Id.* at ¶¶ 15, 19.]

Plaintiff Robert Bradburn was diagnosed with B-Cell Lymphoma, and on February 20, 2019, he had a PowerPort implanted in him by his physician Dr. Stephen Kim to assist with administering chemotherapy. [DE 9 at ¶ 35, 37.] Roughly 9 months after the PowerPort was installed, it was "found to have migrated, retracted and looped on itself near the jugular access site with the distal tip position within the subclavian vein." [*Id.* at ¶ 38.] Bradburn underwent surgery at Elkhart General Hospital and had the PowerPort removed from his body. [*Id.*] The amended complaint does not explain any long-term consequences or injuries on Bradburn's part from the PowerPort, but it is clear the product was implanted in him, did not function inside his body as anticipated, and had to be surgically removed.

Bradburn alleges that because of how the device migrated, the PowerPort was defective in its design and manufacture. He further alleges that Bard provided insufficient warnings about the known dangers associated with PowerPort. To buttress these allegations, Bradburn tells me that "[n]umerous reports of PowerPort catheter migration or dislodgment in the absence of physician error were recorded and reported to [Bard] prior to the implantation of the PowerPort in [him]." [DE 9 at ¶ 42.] Despite these reports, Bard continued to market the device and led Bradburn's healthcare providers to believe that "these failures were caused by physician error" as opposed to the product itself [*Id.* at ¶ 43.] As such, Bard "did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of catheter migration or dislodgment associated with the PowerPort." [*Id.* at ¶ 44.]

Bradburn points to adverse event reports that Bard received between the time that the PowerPort was brought to market and when it was installed in Bradburn. [DE 9 at ¶ 27.] These adverse event reports related to the PowerPort migrating post-implantation. [*Id.*] Bradburn alleges that Bard concealed these adverse event reports from medical professionals through a since-discontinued surveillance and reporting system used by the FDA known as the Alternative Summary Reporting program. [*Id.* at ¶¶ 28-29.] He alleges Bard did nothing to alter the design of the PowerPort or to make it safer or to change its warnings to physicians despite its knowledge of these adverse event reports and problems. [*Id.* at ¶ 33.] And then the device was implanted in Bradburn, migrated, and injured him.

As a result, Bradburn has sued Bard for seven counts, seeking compensatory and punitive damages. Bard has consequently moved to dismiss all seven counts of the amended complaint.

Discussion

My task at the motion to dismiss stage is to determine whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)). In addition to accepting all well-pleaded facts as true, I draw all reasonable inferences in favor of the plaintiff. But purely conclusory allegations, legal or otherwise, are insufficient to state a claim for relief; a plaintiff must allege a baseline level of ***facts*** in order to overcome a motion to dismiss. *See McCauley v. City of Chicago*, 671 F.3d 611, 617 (7th Cir. 2011). But the burden is not immense. Federal Rule of Civil Procedure 8(a)(2) "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting Fed. R. Civ. P. 8(a)(2)). "Specific facts are not necessary, the statement need only 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.'" *Erickson*, 551 U.S. at 93 (quoting *Twombly*, 550 U.S. at 555).

Bradburn's amended complaint contains seven causes of action. Count I alleges "Negligence" under the Indiana Products Liability Act (the "IPLA") Ind. Code 23-20-1-1-, *et seq.*; Count II alleges "Strict Products Liability – Failure to Warn" under the IPLA; Count III alleges "Strict Products Liability – Manufacturing Defect" under the IPLA; Count IV alleges "Strict Products Liability – Design Defect" under the IPLA; Count V

alleges "Breach of Implied Warranty" under the IPLA; Count VI alleges "Breach of Express Warranty" under the IPLA; and Count VII alleges common law fraudulent concealment as it relates to the PowerPort product which was implanted in Bradburn. [DE 9 ¶¶ 51-107.] Bard seeks dismissal of all seven counts.

Bard's first argument targets a number of Bradburn's counts as incorrectly pled under Indiana products liability law. Specifically, it argues that Bradburn pleads causes of actions which may have existed at common law or may exist under other states' laws, but which have been abrogated and streamlined in Indiana by the IPLA. As discussed below, I generally agree with Bard, but that will not result in a wholesale dismissal of the lawsuit.

The IPLA "codified the entire field of products liability" law in Indiana. *Weigle v. SPX Corp.*, 729 F.3d 724, 737 (7th Cir. 2013). By its plain language the statute "governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; ***regardless of the substantive legal theory or theories upon which the action is brought.***" Ind. Code § 34-20-1-1 (emphasis added). There are three theories of liability under the IPLA: "A product can be defective within the meaning of the [IPLA] because of a manufacturing flaw, a defective design or a failure to warn of the dangers while using the product." *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018). That's it. *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981) (holding it was "clear the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort").

Bradburn's rambling complaint makes no effort to track the IPLA whatsoever. And his response to Bard's argument misses the mark. In his brief, Bradburn says that Bard is needlessly focused on "semantics" and mischaracterizes the amended complaint. He points out other cases from the Northern District of Indiana where courts have "declined to dismiss individually pled claims that fall within the purview of the IPLA and have, instead, elected to 'merge' the claims into a single IPLA claim." [DE 15 at 4.]

That's all well and good, and I'll grant him that he can, as a general matter, plead his case in whatever style he wishes (within reason). *See Fisk v. Medtronic, Inc.*, No. 3:17-CV-032 JD, 2017 WL 4247983, at *4 (N.D. Ind. Sept. 25, 2017) ("Whether the theories are designated as Counts 1 through 6, or Count 1(a) through 1(f), both parties understand that Ms. [Bradburn] is pursuing a single cause of action under the IPLA."). But Bradburn's argument does nothing to address the fact he has pled theories of liability which are simply not recognized under Indiana law. That includes, his "Strict Products Liability" claims of failure to warn (Count II) and design defect (Count IV), as well as his breach of implied warranty (Count V); breach of express warranty (Count VI) and fraudulent concealment (Count VII) claims. None of those claims/theories of liability are recognized under the IPLA and are thus not cognizable under Indiana law. Ind. Code § 34-20-1-1. Because those theories are barred as a matter of law, these claims will be dismissed with prejudice. *See Johnson*, 109 N.E.3d at 956; *Timm v. Goodyear Dunlop Tires N. Am. Ltd.*, 309 F. Supp. 2d 595, 600 (N.D. Ind. 2018) ("The IPLA imposes a negligence standard for claims of defective design and failure to warn"); *Kennedy v.*

Guess, Inc., 806 N.E.2d 776, 780 (Ind. 2004) ("Actions for strict liability in tort are restricted to *manufacturers* of defective products.") (citing Ind. Code § 34–20–2–3) (italics in original); *TLB Plastics Corp. v. Procter & Gamble Paper Prod. Co.*, 542 N.E.2d 1373, 1375–76 (Ind. Ct. App. 1989) ("Tortious breach of implied warranty forms the theoretical basis for the strict liability rule adopted in Indiana, but it does not constitute a separate cause of action.").

With that excess fat trimmed from the amended complaint, what is left are Mr. Bradburn's three claims against Bard under the IPLA: 1) for negligently failing to warn; 2) for negligently designing the PowerPort; and 3) a strict liability manufacturing defect claim. Bard moves to dismiss all three of those claims for what it says are pleading inadequacies. In summary, and as discussed below, while Bradburn's amended complaint isn't exactly fulsome when it comes to factual allegations, all it needs to do is allege claims that are plausible. And it has done so on the first two theories under the IPLA—the failure to warn and design defect claims—but it has not alleged enough under the manufacturing defect claim.

First up is Bradburn's failure to warn claim. Bard says this claim fails for two reasons: (1) the amended complaint does not specifically state how or why the warnings were inadequate; and (2) the amended complaint focuses on warnings to Bradburn, the patient, instead of his doctors, which is the incorrect focus under Indiana's "learned intermediary" doctrine. [DE 12 at 10.] Neither of these arguments succeed.

Under the IPLA, in order to state a failure to warn claim a plaintiff must allege facts showing "that the manufacturer or seller failed to exercise reasonable care under

the circumstances . . . in providing the warnings or instructions." Ind. Code § 34-20-2-2; Ind. Code § 34-20-4-2 ("A product is defective under this article if the seller fails to: (1) properly package or label the product to give reasonable warnings of danger about the product; or (2) give reasonably complete instructions on proper use of the product "). Furthermore, under Indiana law, when assessing the adequacy of a warning in the context of a medical device, I do not look at the warnings given to the end-consumer or patient. Instead, I look to the warnings or statements given to doctors, since they are the ones with the relevant technical expertise and are conceptually the ones making decisions for patients as to what device to use. *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1015 (7th Cir. 2020) ("Under Indiana's learned-intermediary doctrine, a medical-device manufacturer can discharge this duty by providing adequate warnings to physicians.").

As I stated above, Bradburn's complaint is not replete with detailed factual allegations concerning the medical device in question and what precisely happened. But it doesn't need to be in order to state a claim. Fed. R. Civ. P. 8(a)(2) (requiring only "a short and plain statement of the claim showing that the pleader is entitled to relief" to state a claim); s*ee also Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010) ("There are no special pleading requirements for product liability claims"). Bradburn alleges that Bard "failed to act reasonably to . . . [a]dequately Inform or warn Plaintiff [and] his prescribing physicians" of the dangers of the PowerPort. [DE 9 at ¶ 34.] Later he states, "Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of catheter migration or dislodgment associated with the PowerPort." [*Id.* at ¶ 44.] Bradburn then alleges that his "physicians relied upon the

representations, including the instructions for use distributed with the product implanted in Plaintiff, and advertisements to Plaintiff's detriment." [*Id*. at ¶ 46.] He also says Bard "failed to exercise due care" by *inter alia*, failing to adequately test the PowerPort, failing to adequately analyze data relating to pre-market tests, failing to exercise due care when advertising the PowerPort, and marketing and selling the PowerPort "without an adequate warning of the significant and dangerous risk of the PowerPort and without proper instructions." [*Id.* at ¶ 53.] More specifically, Bradburn states that "the PowerPort posed a significant and higher risk than other similar devices of device failure" and that Bard "knew that these devices were dislodging and migrating for reasons other than the physician's initial placement of the device or post-implant maintenance." [*Id.* at ¶¶ 59-60.] I think this sufficiently states a claim.

In support of its argument, Bard refers me to several out-of-circuit (mostly district court) decisions that have dismissed products liability cases for failing to adequately plead the "how and why" of a failure to warn claim. *E.g.*, *Oden v. Boston Scientific Corp.*, 330 F. Supp. 3d 877, 891 (E.D.N.Y. 2018); DE 12 at 12 (collecting out-of-circuit cases). But none of those cases, in addition to not being controlling precedent, concerned Indiana law, so they are irrelevant to my inquiry. More on point is the fact that, as noted by Bradburn, federal courts in Indiana have declined to dismiss IPLA claims where a plaintiff has pled at a level similar to what Bradburn does here. *See, e.g.*, *Wortman v. C.R. Bard, Inc.*, No. 1:19-cv-3273-JMS-DLP, 2019 WL 6329651, at *8 (S.D. Ind. Nov. 26, 2019) (denying motion to dismiss where defendant argued the complaint did not state what defendant knew, what physician knew, and specifically how the warning

was inadequate). Like in *Wortman*, Bradburn alleges the basic facts undergirding a plausible claim and that is enough to put Bard on notice of what it must defend against.

Bard's argument concerning the learned intermediary doctrine is similarly unconvincing. As discussed above, the amended complaint identifies that it was Dr. Stephen Kim who implanted the device in Bradburn. [DE 9 at ¶ 35.] It further alleges that the warnings given to Dr. Kim were inadequate and generally states what information was omitted. [*Id.* at ¶¶ 44, 46.] Obviously, it would be great to know at this stage exactly what Dr. Kim knew about the PowerPort and when he knew it, but Bard offers no legal support that such exacting detail is required at this early stage of the lawsuit. Learning these specific details is what discovery is for, and Bard will presumably depose Dr. Kim in advance of summary judgment or trial to learn that information. As pled, there is enough to state a plausible claim and give Bard notice of what the claim against it is.

Next up is Bradburn's design defect claim against which Bard again raises multiple arguments. One of them can quickly be disposed of. In its opening brief, Bard argued that Indiana law requires that a plaintiff plead (and eventually prove) the existence of a safer alternative design as part of a design defect claim. [DE 12 at 14-15.] But in a footnote in its reply, it concedes it was wrong on the law. [DE 14 at 8, n. 2.] Literally two days before Bard filed its motion to dismiss, the Seventh Circuit clarified and abrogated its prior precedent on this issue, deferring, as it had to, to the Indiana Supreme Court's jurisprudence. *Kaiser*, 947 F.3d at 1012 ("[W]e have generally read the IPLA to require evidence of a reasonable alternative design in all design-defect cases . . .

The Indiana Supreme Court rejected that interpretation of the Act . . ."); *id.* at 1013 ("The Indiana Supreme Court has spoken clearly and unequivocally: the IPLA does *not* require evidence of a reasonable alternative design to establish design-defect liability.") (italics in original).[1] With no ambiguity about a safer alternative design ***not*** being an element for a design defect claim under the IPLA, there is nothing wrong with Bradburn arguably not alleging one in his amended complaint.

Bard's remaining argument on the design defect claim doesn't fair much better. It says that Bradburn "does not identify any particular problem in the design" of the PowerPort. [DE 12 at 15.] Again, I disagree. Under the IPLA, all Bradburn is required to allege are facts which would tend to show that "the manufacturer or seller failed to exercise reasonable under the circumstances in designing the product." *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 209 (Ind. 2010) (quoting Ind. Code § 34-20-2-2). He meets that requirement.

In the amended complaint, Bradburn alleges that the PowerPort was sold without "a cuff made from polyethylene terephthalate, the purpose of which is to promote tissue ingrowth at the locus of the cuff, anchoring the catheter and reducing the risk of catheter displacement and migration." [DE 9 at ¶ 17.] Bradburn further states that "[t]his design feature is included in multiple catheters manufactured and

[1] Bard probably should have anticipated its argument would not hold much sway with me, as the Seventh Circuit's decision in *Kaiser* was affirming my opinion that Indiana law did not require proof of a safer alternative design as part of a design defect claim. *See Kaiser v. Johnson & Johnson*, 334 F. Supp. 3d 923, 934 (N.D. Ind. 2018), *aff'd*, 947 F.3d 996 (7th Cir. 2020).

distributed by Defendants." [*Id.*] Considering Bradburn's chief allegation of how the PowerPort failed him is that it migrated within his body and "looped on itself near the jugular access site" [*id.* at ¶ 38], that seems like a very relevant and plainly stated design defect. And he alleges that Bard received "numerous reports of PowerPort catheter migration" prior to when the device was implanted in Bradburn. [*Id.* at ¶ 42.] Therefore, he sufficiently states a plausible design defect claim.

Finally, I will address Bradburn's manufacturing defect claim. Unlike failure to warn or design defect, this is a strict liability claim. *Simpson v. Gen. Dynamics Ordnance & Tactical Sys.-Simunition Operations, Inc.*, 429 F. Supp. 3d 566, 576 (N.D. Ind. 2019); Ind. Code § 34-20-2-3. "A product contains a manufacturing defect when it deviates from its intended design." *Hathaway v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669, 673–74 (N.D. Ind. 2012) (citation omitted). Bard's argument is that the amended complaint is wholly lacking in facts and instead contains only "vague, conclusory, and self-serving assertions [which] fail to put Defendants on notice of the alleged error in the manufacturing process for the PowerPort[.]" [DE 12 at 17.] Setting aside the fact that a complaint, filed to initiate a lawsuit against a defendant, is always going to be "self-serving" for a plaintiff (it would be curious if it it didn't serve their cause), I agree with Bard that Bradburn has not met his pleading burden on this claim.

To decide the issue, both sides direct me to the Seventh Circuit's decision in *Bausch v. Stryker Corp.*, and I agree it dictates the result in this case. In *Bausch*, the plaintiff alleged that a hip replacement product was defective, both in design and in its manufacture. *Bausch*, 630 F.3d at 558-559. The district court dismissed the complaint

which included a manufacturing defect claim under Illinois law, with prejudice. The Seventh Circuit then reversed, finding that the plaintiff had met their pleading burden considering "the amount of information available to them." *Id.* at 561 (citation omitted).

Like the Seventh Circuit in *Bausch*, I am sympathetic to the position plaintiff is in at the start of a medical device products liability case—there's an obvious information imbalance between a plaintiff-patient and a defendant-manufacturer at the outset. *See Bausch*, 630 F.3d at 560 ("[T]he victim of a genuinely defective product . . . may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem."). But here, Bradburn offers no facts whatsoever as to what the manufacturing defect here allegedly was, which the plaintiffs in *Bausch* clearly did. In *Bausch*, the plaintiff told a detailed story about the product in question and its purported manufacturing defects:

> According to the original complaint, by early 2005, the defendants received complaints that the Trident was failing after it was implanted. Defendants recalled a batch of Trident components in March 2006 because of "dimensional anomalies." The FDA conducted an inspection at the defendants' Ireland manufacturing facility from October 31 to November 3, 2006, and, following the inspection, informed the defendants of "numerous deficiencies [in the Trident] manufacturing and inspection processes." Six days before plaintiff Bausch's surgery, "after several months of inadequate response to the FDA findings by the defendants," the FDA issued a letter to defendants on March 15, 2007 warning that the Trident was "adulterated due to manufacturing methods ... not in conformity with industry and regulatory standards." A device, bearing the same catalogue number as the device allegedly not in compliance with regulations, was then implanted in Bausch's body the next week. The device in Bausch's body failed and the same device was later recalled.

Bausch, 630 F.3d at 559. Bradburn's amended complaint is missing anything of that nature. He doesn't allege, for example, any facts which allege Bard knew or should have known it was manufacturing defective products, any specific process or standard that Bard wasn't following when it was manufacturing the PowerPort, or that Bard recalled any PowerPorts because of defects. *See Mikesell v. St. Jude Med., Inc.*, No. 3:16-CV-304-JD-MGG, 2017 WL 9565366, at *6 (N.D. Ind. Feb. 2, 2017), *report and recommendation adopted,* No. 3:16-CV-304 JD, 2017 WL 655862 (N.D. Ind. Feb. 17, 2017) ("Plaintiffs here allege nothing as to St. Jude's knowledge of defects or any recall of the Riata Lead before it was implanted into Mr. Mikesell in 2005.") (dismissing manufacturing defect claim in medical device products liability action). That's fatal to the claim at this stage. A plaintiff may not need to allege a multitude of facts to survive a motion to dismiss, but they must allege more than mere conclusions. I will thus dismiss Bradburn's manufacturing defect claim, without prejudice. If Bradburn has or learns additional facts he can allege to support this claim, he may seek leave to file an amended complaint.

Conclusion

For the foregoing reasons, Defendants' Motion to Dismiss [DE 11] is GRANTED, in part, and DENIED, in part. To the extent Count II (failure to warn) and IV (design defect) are premised on strict liability, they are DISMISSED, with prejudice. Likewise, Counts V, VI, and VII, are DISMISSED, with prejudice. Count III, the claim premised on a manufacturing defect, is DISMISSED, without prejudice.

Summed up, this case is proceeding on an IPLA claim for, (1) failure to warn, and (2) defective design, both of which are negligence-based theories of liability under Indiana law. No amended complaint needs to be filed at this point, however, even if they are not precisely pled in the amended complaint. *See Bausch*, 630 F.3d at 559. (explaining that when a court dismisses less than the full complaint, it is "not even necessary" for a plaintiff to file a "cleaner" or new version of the complaint so long as it is evident "as to the proper scope of claims that can survive the legal challenge").

SO ORDERED on June 9, 2020.

/s/ Philip P. Simon
PHILIP P. SIMON, JUDGE
UNITED STATES DISTRICT COURT